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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,590	05/26/2005	Shojiro Matsuda	10873.1686USWO	9228

52835 7590 02/08/2007

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EXAMINER	
DAVIS, JENNA L	
ART UNIT	**PAPER NUMBER**
1771	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,590	MATSUDA ET AL.	
	Examiner	Art Unit	
	Jenna Davis	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-28* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 and 11-14, 17-26, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 022 031 to Matsuda in view of WO 97/07833 to Pressato.

Matsuda teaches a medical film comprising a gelatin film (abstract) and a reinforcing material such as a non-woven fabric wherein the gelatin coating covers one or both sides or a part of a whole of the reinforcing member. Matsuda teaches proving the gelatin coating covering one or both sides or a part or whole of the reinforcing member but is not specific as to the materials being integrated with each other. Pressato also teaches a material for preventing post-surgical adhesion and describes at page 6 the incorporation of a hyaluronic acid with a fabric. Pressato teaches using such gels and fabrics or membranes in combination and further teaches crosslinking the hyaluronic acid gels (page 15, lines 8-28). The material may be in sheet form (page 27, lines 3-4). The fabric may be a nonwoven or a woven fabric and may be needle punched (page 25, line 22). The reinforcing fabric may have a basis weight between 20 and 500 gms (page 6, lines 25-28) which overlaps the range of claim 12, and may have a thickness of 200 microns to 1.5 mm which overlaps the range of claim 13. See page 6. It is not seen that the specific process steps set forth in claims 20-24 distinguish the presently claimed article from the prior art articles as the references expressly suggest crosslinking the gels used therein. The

courts have held that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda in view of Pressato as applied to the claims above, and further in view of Melican (US 6599323).

The teachings of Matsuda and Pressato are set forth above. Neither reference teaches the use of a knit fabric as the reinforcement provided therein. As shown by Figure 6 of Melican the art of bioabsorbable medical devices had known to provide knit mesh materials as reinforcements for such materials. To have provided a knit as the reinforcement desired by Matsuda and Pressato would have been obvious to a person having ordinary skill in the art as the use of a known reinforcement for its intended and desired function. Note that at column 6, last paragraph, Melican discloses the equivalence of woven, knitted, warp knitted, non-woven and braided structures.

Claim16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda in view of Pressato as applied to the claims above, and further in view of Jurgens (US 5854381).

The teachings of Matsuda and Pressato are set forth above. The references teach various bioabsorbable materials, but are not specific to a lactic acid-caprolactone copolymer. As shown by Jurgens to was known to provide a bioabsorbable polymer comprising lactide and caprolactone in a molar ration between 90:10 and 70:30. It would have been obvious to a person

having ordinary skill in the art to have provided such a bioabsorbable material to the material of Matsuda as modified by Pressato in order to provide a polymer that is suitable for preventing surgical adhesions.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda in view of Pressato as applied to claim1 above, and further in view of Consolazio (US 4374063).

Neither Matsuda nor Pressato are specific to the amount of endotoxin present in the gels taught therein, however Consolazio teach that the pharmaceutical field requires gels that are free from endotoxins. It would have been obvious to a person having ordinary skill in the art to have provided an endotoxin free gel since endotoxins are bad for the body.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-10, and 12-24 of copending

Application No. 10/480744. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to gelatin films carrying a reinforcing material.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jenna Davis whose telephone number is 571-272-3357. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jenna Davis
Primary Examiner
Art Unit 1771